Listing of Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently amended) A capsule for sustained release of drugs including a combination of acetaminophen of from 100 mg to 1,000 mg and tramadol or its salts of from 15 mg to 150 mg comprising:

1) ~~An~~ an immediate release portion comprising 25%-75% of the total effective amount of the drugs in the form selected from pellets, beads, granules and mini-tablets~~.~~; and

2) ~~A~~ a sustained release portion comprising:

a. 25%-75% of the total effective amount of the drugs in the form selected from pellets, beads, granules and mini-tablets; and

b. a gelling polymer in an amount by weight of the capsule of 6% to 50%.

~~6%-50% of gelling polymers of the capsule total formulation, and said the sustained release portion may or may not comprise an enteric coating at a level of 5%-40% of the total formulation.~~

2. (Currently amended) ~~A capsule, as set forth in claim 1,~~ The tablet of claim 1 releases 25%-60% of the ~~total~~ drugs in the first hour in a simulated gastric fluid dissolution media, 50%-90% of the ~~total~~ drugs in the first four hours and not less than 80% of the ~~total~~ drugs in the first 12 hours in a simulated intestinal fluid dissolution media using USP dissolution method II at 50 rpm.

3. (Currently amended) ~~A capsule, as set forth in claim 1, comprises at least one~~ The capsule of claim 1 wherein the gelling polymer is selected from the group consisting of ~~selected from~~ hydroxy propyl methylcellulose, hydroxypropyl ethylcellulose, hydroxypropyl cellulose, hydroxy ethylcellulose, methylcellulose, xantham gums, alginate salts, polyethylene oxide, carboxyvinyl polymer, or a salt of a carboxymethyl cellulose, said gelling polymer having a

viscosity within the range of from about 60 to about 7,000,000 centipoises~~, and preferably from about 100 to about 100,000 centipoises,~~ in a 2% by weight water solution at 25.degree. C., as measured by a Brookfield LV viscometer.

4. (Currently amended) The capsule of claim 1 wherein the pellets, beads, granules and mini-tablets of the sustained release portion ~~in the capsule, as set forth in claim 1, may or may not be~~ are coated with an enteric polymers selected from the group consisting of polyacrylate material, cellulose acetate phthalate, cellulose phthalate hydroxy propyl methyl ether, polyvinyl acetate phthalate, hydroxy propyl methyl cellulose acetate succinate, cellulose acetate trimellitate, or a shellac.

5. (Currently amended) A tablet for sustained release of drugs including a combination of acetaminophen of from 100 mg to 1,000 mg and tramadol or its salt of from 15 mg to 150 mg comprising:

1) ~~A~~ a sustained release portion comprising:

a. 25%-75% of the total effective amount of the drugs; and

b. ~~6%-50% of~~ a gelling polymers in an amount by weight of the tablet from 6% to 50% ~~of the total formulation, and said the sustained release portion may or may not comprise an enteric coating at a level of 5%-40% of the total formulation~~; and

2) ~~An~~ an immediate release portion comprising 25%-75% of the total effective amount of the drugs, layered or compressed on the sustained release portion.

6. (Currently amended) ~~A tablet, as set forth in claim 5,~~ The tablet of claim 5 releases 25%-60% of the ~~total~~ drugs in the first hour in a simulated gastric fluid dissolution media, 50%-90% of the ~~total~~ drugs in the first four hours and not less than 80% of the ~~total~~ drugs in the first 12 hours in a simulated intestinal fluid dissolution media using USP dissolution method II at 50 rpm.

7. (Currently amended) ~~A tablet, as set forth in claim 5, comprises at least one~~ The tablet of claim 5 wherein the gelling polymer is selected from the group consisting of ~~selected from~~

hydroxy propyl methylcellulose, hydroxypropyl ethylcellulose, hydroxypropyl cellulose, hydroxy ethylcellulose, methylcellulose, xantham gums, alginate salts, polyethylene oxide, carboxyvinyl polymer, or a salt of a carboxymethyl cellulose, said gelling polymer having a viscosity within the range of from about 60 to about 7,000,000 centipoises~~, and preferably from about 100 to about 100,000 centipoises,~~ in a 2% by weight water solution at 25.degree. C., as measured by a Brookfield LV viscometer.

8. (Currently amended) ~~The sustained release portion, as set forth in claim 5, may or may not be~~ The tablet of claim 5 further comprising a coating on the sustained release portion of an enteric polymer selected from the group consisting of ~~coated with enteric polymers selected from~~ polyacrylate material, cellulose acetate phthalate, cellulose phthalate hydroxy propyl methyl ether, polyvinyl acetate phthalate, hydroxy propyl methyl cellulose acetate succinate, cellulose acetate trimellitate, or a shellac.

9. (Currently Amended) A sustained release dosage form of drugs including a combination of acetaminophen and tramadol comprising:

1) A sustained release portion comprising:

a. 25%-75% of the total effective amount of the drugs; and

b. 6%-50% of a gelling polymers of the ~~total formulation~~ dosage form~~, and said the sustained release portion may or may not comprise an enteric coating at a level of 5%-40% of the total formulation~~;

2) An immediate release portion comprising 25%-75% of the ~~total effective amount of~~ drugs, layered or compressed on the sustained release portion.

10. (Currently amended) ~~A sustained release dosage form, as set forth in claim 9,~~ The dosage form of claim 9 releases 25%-60% of the ~~total~~ drugs in the first hour in a simulated gastric fluid dissolution media, 50%-90% of the ~~total~~ drugs in the first four hours and not less than 80% of the ~~total~~ drugs in the first 12 hours in a simulated intestinal fluid dissolution media using USP dissolution method II at 50 rpm.

11. (Currently amended) ~~A sustained release dosage form, as set forth in claim 9, comprises at least one~~ The dosage form of claim 9 wherein the gelling polymer is selected from the group consisting of hydroxy propyl methylcellulose, hydroxypropyl ethylcellulose, hydroxypropyl cellulose, hydroxy ethylcellulose, methylcellulose, xantham gums, alginate salts, polyethylene oxide, carboxyvinyl polymer, or a salt of a carboxymethyl cellulose, said gelling polymer having a viscosity within the range of from about 60 to about 7,000,000 centipoises~~, and preferably from about 100 to about 100,000 centipoises,~~ in a 2% by weight water solution at 25.degree. C., as measured by a Brookfield LV viscometer.

12. (Currently amended) ~~The sustained release portion, as set forth in claim 9, may or may not be coated with~~ The dosage form of claim 9 further comprising an enteric polymer coating on the sustained release portion, the enteric polymers being selected from the group consisting of polyacrylate material, cellulose acetate phthalate, cellulose phthalate hydroxy propyl methyl ether, polyvinyl acetate phthalate, hydroxy propyl methyl cellulose acetate succinate, cellulose acetate trimellitate, or a shellac.